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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,872	10/12/2001	Anthony Toranto	ANGL-06602	2860

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EXAMINER
DAVIS, DEBORAH A

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,872	TORANTO ET AL.	
	Examiner	Art Unit	
	Deborah A Davis	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12-4-02* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 18-27* is/are pending in the application.

4a) Of the above claim(s) ~~*16 and 17*~~ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 18-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's response to the Office Action mailed December 04, 2002 (Paper #9) is acknowledged. Currently, claims 16-17 and 28-73 are cancelled. Claims 1-15 and 18-27 are pending with 1, 18 and 19 being amended and under consideration.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-15 and 18-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of "oral fluid" in the amended claim 1 is not provided in the specification. Although saliva is considered oral fluid, blood, phlem and pus is oral fluid as well and support in the specification only provides for saliva. Applicant is invited to show support for this limitation.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, and 11are rejected under 35 U.S.C. 102(b) as being anticipated by Manautou et al (USP#3,875,013).

Manautou et al teaches a test that provides for detecting the fertile period or the presence of pregnancy in a female. In one embodiment, the saliva of a female is tested orally, in which her tongue wets the test paper and waits about 20 minutes forming a color. The test strips are impregnated with reagents for the practice of the invention as recited in claims 1-6 (col. 3, lines 20-25). The test strips is then compared to a standard color card that has a series of color spots similarly developed from known concentrations of the color compound p-nitrophenol (chromogen) as recited in claims 2, and 11 (col. 3, lines 39-58).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 5-6, 8-15, and 18-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manautou et al in view of Stuart C. Bogema (USP#6,248,598).

The teachings of Manautou et al are set forth above and differ from the instant invention by not specifically pointing out that the reaction site comprise of an antibody or the length of time reaction site is held in the mouth of the subject.

However, Stuart C. Bogema teaches a device that provides a rapid analysis of saliva samples while also providing a convenient assay method that can be used by non-laboratory personnel without risk of user errors (see abstract). A solid support (strip) made of a suitable absorbent material is inserted into the patient's mouth that provides for sufficient absorption of saliva for about 10-120 seconds (col. 7, lines 15-65). A portion of the solid support (strip) includes a visual reading area on which is directly bound a binding partner, a protein such as an antibody that specifically binds an analyte that comprise of a colored label (col. 8, lines 12-23). The results can be seen with the naked eye (col. 8, lines 52-54).

It would have been obvious to one of ordinary skill in the art to incorporate an antibody as taught by Stuart C. Bogema and utilize it in the reaction site of the test strip as taught by Manautou et al to specifically bind the analyte being detected in the saliva. It would have also been obvious to one of ordinary skill in the art to modify the test strip of Manautou et al to perform an assay test quickly and simply thereby eliminating the need for a technician or a laboratory setting that should afford benefits both in terms of convenience and reduced costs. With respect to claims 20-27, which are features of remaining dependent claims that are either specifically described by the references (e.g., ethanol, methanol detection col. 11, line 11) or constitute obvious variations which are routinely modified in the art and which have not been described as critical to the

practice of the invention, it would have been further obvious to one having ordinary skill the art at the time the invention was made to modify the method of Manautou et al to detect any known analyte of interest, especially since it has been held that the provision of adjustability, where needed, involves only routine skill in the art. In re Stevens, 101 USPQ 284 (CCPA 1954). Absent evidence to the contrary, the detection of known analytes in the instant invention is viewed as routine optimization in prior art. With respect to claims 18-19, it would have been further obvious that the teachings of the instant reference would encompass these known safety features, especially when patient is undergoing oral testing for detection of an analyte wherein said test utilizes a chromogen, as taught Manautou et al one skilled in the art would assume that a chromogen that is used on a patient's tongue, a non-toxic, non-irritating and one that is not a known carcinogen will be utilized.

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Manautou et al in view Andrew Kindler (USP#5,494,831).

The teachings of Manautou et al are set forth above and differ from the instant claim in not teaching the use of a biosensor.

However, Andrew Kindler teaches an electrochemical immunosensor (biosensor) which uses electrical signals to measure binding events. Signal generating means develop an electrical signal at the sensing electrode such that a response current is produced through the sensing electrode. The response current has measurable signal

that are dependent upon the number of complexes formed within the sample concentration (see abstract).

It would have been obvious to one of ordinary skill in the art to modify the teachings of Manautou et al to include the use of a biosensor as taught by Andrew Kindler to not only detect the analyte in a sample, but to also measure quantities of the binding events (col. 3, lines 30-40).

Response to Arguments

9. Applicant's arguments filed March 17, 2003 that Vodian et al fails to teach limitations in view of amended claims is found persuasive and therefore rejection has been withdrawn.

10. Applicant's aregurnents filed March 17, 2003 that Jangbir S. Sangha fails to teach limitations in view of amended claims is found persuasive and therefore rejection has been withdrawn.

11. Applicant's arguments filed March 17, 2003 has been fully considered but not found persuasive. Applicant's argument that the Manautou et al reference does not provide a reaction site that produces a detectable signal in the prescence of an analyte and that said reaction site is not exposed to patient's mouth is not found persuasive because the oral test strip is impregnated with a color developing compound and buffers that produces a color during the ovulation and fertility of the female and no color change at other times (col. 3, lines 30-58). Manautou et al teaches that the oral test strip is placed on the patient's tongue wherein the tongue is inside of the patients mouth which

meets the limitation of the reaction site being placed in the patients mouth. Applicant's argument that p-nitrophenol of Manautou et al is not a non-toxic chromogen has been considered but not found persusasive because at certain levels of concentrations, many chemicals can be toxic. Manautou et al teaches the use of an oral test strip that comprise of p-nitrophenol that is apparently safe enough to use orally. Further, it would be assumed the instant reference would encompass these known safety features, especially when patient is undergoing oral testing for detection of an analyte wherein said oral test strip utilizes a chromogen, one skilled in the art would assume that a chromogen that is non-irritating and one that is not a known carcinogen will be utilized. Based on the above arguments, the Manautou et al reference is hereby maintained.

Conclusion

15. For reasons aforementioned, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

Deborah A. Davis
CM1, 7D16
June 2, 2003

LONG V. LE
SUPERVISORY PATENT EXAMINER
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6/02/03